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510(K) Summary of Safety and Effectiveness

General Information

Submitter's Name:	BioMedix, Inc.
Address:	4215 White Bear Parkway
	St. Paul, MN 55110
Telephone:	(651)762-4010
Contact Person:	Will Rogers
Date Prepared:	November 5th, 2007
Registration Number:	213492
Owner/Operator Number:	9032550

NOV 2 1 2007

Device

Name:	PADnet+
Trade Name:	PADnet+
Common Name:	Plethysmograph
Classification Name:	Blood Flow Monitor
Product Code:	JOM
Class:	II
Regulation Number:	870.2780

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Identification of Legally Marketed Devices

Name:	Flostat Vascular Lab	PADnet Lab
K Number:	K973644	K042616
Date Cleared:	December 23, 1997	October 12, 2004

Description of the Device

The BioMedix PADnet Lab is a non invasive cardiovascular blood flow monitor. It is intended for use in the early detection of peripheral vascular disease. The PADnet Lab has been tested to the following standards.

- EN60601-1 Electrical Safety
- EN60601-1-2 EMC
- ISO 10993-1 Biological Evaluation

The BioMedix PADnet+ is a non invasive cardiovascular blood flow monitor. It is intended for use by trained medical professionals in a hospital or clinic. It is not to be operated in an explosive atmosphere or in the proximity to any equipment that has the potential to generate a sufficiently large electromagnetic field as to interfere in any manner with the operation of the PADnet Lab+.

The BioMedix PADnet Lab is a Prescription Device, not life supporting or life sustaining, not an implant, supplied **non-sterile** with pressure cuffs. It requires a Personal Computer with the following requirements:

- Windows 2000 Operating System or Higher
- 128 MB RAM
- 20 GB Free Hard Disk Space
- 600 MHZ Processor or Higher

Intended Use Statement

The BioMedix PADnet+ is a non invasive device used to gage the lower extremity arterial and venous system, using pulse volume recording, oscillometric segmental systolic blood pressure and photo plethysmograph, to assist in the identification of vascular disease. It is intended to be used by healthcare professionals in a hospital or clinic environment. The device is not intended for pediatric or fetal use. It is also not intended for the use on or near non intact skin.

Components/Part Numbers

Description	BioMedix Part Number
1 – USB Cable	100-1600
1 – Cuff Kit	7201
1 - BioMedix PADnet+ (Software Program CD ROM)	400-210
1 – AC Power Cord	350-215
1 – PADnet+ Operators Manual	10650

Table of Comparisons

The attached summary table compares the new device (PADnet+) to the predicate device: Flowstat Vascular Lab & PADnet Lab.

Discussion of Similarities and Differences

The PADnet+, PADnet Lab and the Flowstat Lab have the following similarities:

- Pulse Volume Recording
- Patient Population
- Environment
- Power Source
- Software Controls
- Cuff Deflation Rate
- Operating Environment

- Storage Environment
- Safety Standards
- EMC
- Prescription Device
- Cuff Bladder Deflation
- Inflation Method
- Cuff Sizes
- Clinical Reports
- Printed Reports
- Supplied Non-Sterile

The differences, with comments, are the following:

- Segmental Pressure flow sensor – The PADnet Lab uses Oscillometric not distal flow sensor.
- Weight – PADnet Lab is significantly less.
- Data acquisition – PADnet Lab is single site not bilateral.
- Size – PADnet Lab is slightly smaller.
- PADnet+ and Flowstat Lab both have photoplethysmograph.

Thus, even though the PADnet+ is not identical to the PADnet Lab and Flowstat Vascular Lab, we at BioMedix believe it should be granted substantial equivalence because:

- It has the same intended use as the predicate devices.
- It has the same technical characteristics as the predicate devices and does not raise any new types of safety or effectiveness concerns.
- It has combined the PPG from the Flowstat Vascular Lab with the original design of the PADnet Lab. Both products are predicate devices for the PADnet+.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 1 2007

BioMedix, Inc.
c/o Mr. Will Rogers
Chief Technology Officer
4215 White Bear Parkway
St. Paul, MN 55110

Re: K073146
PADnet+
Regulation Number: 21 CFR 870.2780
Regulation Name: Hydraulic, pneumatic or photoelectric plethysmographs
Regulatory Class: Class II (two)
Product Code: JOM and JAF
Dated: November 02, 2007
Received: November 08, 2007

Dear Mr. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K073146

Indications for Use

510(k) Number (if known):_____

Device Name: PADnet+

Indications for Use:

The BioMedix PADnet+ is a non invasive device used to gage the lower extremity arterial and venous system, using pulse volume recording, oscillometric segmental systolic blood pressure and photo plethysmograph, to assist in the identification of vascular disease. It is intended to be used by healthcare professionals in a hospital or clinic environment. The device is not intended for pediatric or fetal use. It is also not intended for the use on or near non intact skin.

User Profile:

Patient Population: Male/Female, Adults
Environment of Use: Hospitals or Clinics

Prescription Use ____x____ AND/OR Over-The Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of Device Evaluation (ODE)

for BDZ

(Division Sign-Off)
Division of Cardiovascular Devices

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